## NOTICE OF INTENT

## Department of Health and Hospitals Office of the Secretary Bureau of Health Services Financing

Medicaid Pharmacy Benefits Management System Point-of-Sale.Prospective Drug Utilization Program

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing proposes to adopt the following rule in the Medicaid Program as authorized by R.S. 46:153 and pursuant to Title XIX of the Social Security Act, Section 1927(g) and (h) and as directed by the 1995-96 General Appropriation Act, which states: "The Secretary shall implement reductions in the Medicaid Program as necessary to control expenditures to the level approved in this schedule. The Secretary is hereby directed to utilize various cost containment measures to accomplish these reductions, including but not limited to pre-certification, pre-admission screening, and utilization review, and other measures as allowed by federal law".

Section 1927(g) as added by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) provides that in order for states to receive federal financial participation for covered outpatient drugs, the state must have in operation a drug use review program. This Drug Utilization Review Program must consist of prospective drug review, retrospective drug use review, the application of explicit predetermined standards, and an educational program. The purpose of this program is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate and medically necessary, and that they are not likely to result in adverse medical effects. This section of the Act mandates detailed requirements for conducting drug use reviews and for the State Drug Utilization Review Boards. The Department of Health and Hospitals Board of Pharmacy adopted a Rule on August 20, 1992 (Louisiana Register Volume 19, No.8) which incorporated these requirements under the Professional and Occupational Standards for pharmacists. Section 1927(h) also added by the Omnibus Budget Reconciliation Act of 1990 encourages states to establish a point-of-sale electronic claims management (ECM) system for processing claims for covered outpatient drugs which is capable of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims and assisting pharmacists and other authorized persons in applying for and receiving payment. Regulations at Section 456.705(a) and (b)(1) require review of drug therapy based on predetermined standards at the point-of-sale before each prescription is filled or delivered to a recipient. The proposed rule provides integration of the pharmacy operations into a pharmacy benefit management system for the enhanced operation of the Louisiana Drug Utilization Review Program and the Medicaid State Plan by including prospective drug review at the point-of-sale, an educational program, and implementation of the Point-of-Sale Electronic Claims Management.

The implementation of the following proposed rule will integrate and enhance current efforts to provide optimal pharmaceutical services and to maintain program integrity. Integration of the Pharmacy Program's existing components, Retrospective Drug Utilization Review, Formulary Management, Claims Management, Patient Education Program, Pharmacy Provider Network and Provider Service with the Louisiana Medicaid Pharmacy Benefits Management's new components of Enhanced Pharmacy Network, Pharmacy Provider Help Desk, Point-of-Sale Electronic Claims Management Network, Point of Service Prospective Drug Utilization Review System and Patient, Physician and Pharmacist Education System will enhance the existing features to allow for greater capability to determine if appropriate pharmaceuticals are being utilized for optimal disease and outcomes management of the patient. The Department of Health and Hospitals has initiated an Interdisciplinary Medicine and Pharmacy Team to assist in the development of various educational and intervention components. The conversion of the current Drug Utilization Review Program into an enhanced on-line electronic prospective one will reduce costly duplicate drug therapy, prevent potential drug to drug interactions, assure appropriate drug use, dosage and duration of therapy. In addition the electronic system will provide drug information and education to providers. This electronic system will enable the Medicaid Program to monitor prescribing patterns and recipient drug utilizations patterns. Analyses of data derived from the Point- of- Sale/PRO-DUR system will allow for timely interventions for those providers and/or recipients. The point-of-sale technology will integrate provider networks which will allow for better management of disease states.

This system will be administered by the Bureau of Health Services Financing with contractual agreements for programmatic and administrative support with the Northeast Louisiana University, School of Pharmacy, the fiscal intermediary for the Medicaid Program and an audit firm. The on-line Point-of-Sale System will provide accurate and efficient information including online, real-time eligibility, claims

data capture, claims adjudication and claims payment. Also this system will integrate provider networks which will allow for better management of the patient's health care. The department initiated emergency rulemaking to implement these initiatives effective January 1, 1996 (*Louisiana Register* Volume 22, No.1).

## Proposed Rule

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing proposes to implement the Louisiana Medicaid Pharmacy Benefits Management System (LMPBM) which includes a Point-of-Sale/Prospective Drug Utilization Review component. The department reserves the right for ultimate decision making relative to certain drug class information and drug contraindications or interactions.

The LMPBM Program will integrate the following administrative components of the Medicaid Pharmacy Program.

- 1. Formulary Management. The formulary is managed through the use of the Federal Upper Limits (FUL) and the Louisiana Maximum Allowable Costs (LMAC) limitations. Federal Upper Limits and Louisiana Maximum Allowable Costs limitations provide for dispensing of multiple source drugs at established limitations unless the prescribing physician specifies that the brand product is medically necessary for a patient. Establishment of co-payments also provides for formulary management. The Medicaid Program has established a broad formulary with limited exceptions.
- 2. Reimbursement Management. The cost of pharmaceutical care is managed through Estimated Acquisition Costs (EAC) of drug ingredient costs through Average Wholesale Price (AWP) discounting, the Louisiana Maximum Allowable Costs LMAC) limitations and compliance with Federal Upper Limits (FUL) regulations, and the establishment of the maximum allowable overhead costs, drug rebates and copayments.
- 3. Claims Management. The claims management component is performed through the processing of pharmacy claims against established edits. Claim edit patterns and operational reports are analyzed to review the effectiveness of established edits and to identify those areas where the development of additional edits are needed.
- 4. Program Integrity. Program Integrity is maintained through the following mechanisms: Retrospective Drug Utilization Review, Lock-In Program for patient education, Surveillance and Utilization Review Program which provides for on-going review processes for misutilization, abuse and fraud, and audits of the providers of the Pharmacy Program.
- 5. Pharmacy Provider Network. Enrolled Medicaid pharmacy providers are required to comply with all applicable federal and state laws and regulations.
- 6. The Point-of-Sale Prospective Drug Utilization Review System. This on-line Point-of-Sale System provides electronic claims management to evaluate and improve drug utilization quality. Information about the patient and the drug will be analyzed through the use of eight therapeutic modules in accordance with the standards of the National Council of Prescription Drug Plan. The purpose of Prospective Drug Utilization Review is to reduce in duplication of drug therapy, prevent drug to drug interactions, and assure appropriate drug use, dosage and duration. The PRO-DUR modules may screen for drug interactions, therapeutic duplication, improper duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission sends on-line messages to pharmacists informing them of potential drug-related problems and the pharmacists must document their responses by using interventions codes. By using these codes pharmacists will document prescription reporting and outcomes of therapy for Medicaid recipients.
  - A. POS/PRS-DUR Requirements Provider Participation
- 1. A point-of-sale enrollment amendment and certification is required prior to billing POS/PRO-DUR system. Annual recertification is required.
- 2. All Medicaid enrolled pharmacy providers will be required to participate in the Pharmacy Benefits Management System.
- 3. All Medicaid enrolled pharmacy providers whose claim volume exceeds 100 claims or \$4,000 per month and all providers enrolled on January 1, 1996 will be required to participate in Point-of-Sale System. Long Term Care pharmacy provider claims may be processed through Electronic Media Claims (EMC).
- 4. Providers accessing the POS/PRO-DUR system will be responsible for the purchase of all hardware for connection to the switching companies and any fees associated with connection or transmission of information to the fiscal intermediary. The Bureau of Health Services Financing will not reimburse the provider for any initial on-going fees incurred by the provider to access the POS/PRO-DUR system.
- 5. Providers are required to verify eligibility with the monthly eligibility card and a copy of the card should be retained for processing the claim.

- 6. Pharmacy providers and physicians may obtain assistance with clinical questions from the Northeast Louisiana University, School of Pharmacy.
- 7. Physicians and pharmacy providers will be required to participate in the educational and intervention features of the Pharmacy Benefits Management System.
- B. Recipient Participation. Pharmacy patients are encouraged to take an active role in the treatment or management of their health conditions through participation in patient counseling efforts with their physicians and pharmacists.
- C. Disease and Outcomes Management. Disease management will be focused on improving the drug therapy for certain disease states by developing procedures to assure direct interventions and increasing compliance of patients. Patient populations will be targeted for disease therapy monitoring and educational efforts.
- D. Peer Counseling and Conference Management. The department will analyze data for individual prescribers and pharmacists. Quality management strategies will be used for peer counseling and conferences with precribers and/or pharmacists to assure appropriate prescribing and dispensing.

Interested persons may submit written comments to Thomas D. Collins, Bureau of Health Services Financing, Box 91030, Baton Rouge, LA 70821. He is responsible for responding to inquiries regarding this proposed rule. A public hearing will be held on this matter at 9:30 a.m., Tuesday, June 25, 1996, in the first floor auditorium of the Department of Transportation and Development, 1201 Capitol Access Road, Baton Rouge, LA. At that time all interested parties will be afforded an opportunity to submit data, views or arguments, orally or in writing. The deadline for the receipt of all comments is 4:30 on the day following the public hearing.

Bobby P. Jindal Secretary

## FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Pharmacy Benefits Management Systems Prospective/DUR Program

ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that implementation of this proposed rule will decrease expenditures for the Medicaid Program by approximately \$3,398,424 for SFY 1996; \$11,813,400 for SFY 1997; and \$5,906,700 for SFY 1998. The state portion of these savings are as follows: SFY 1996 \$929,469; SFY 1997 \$3,320,747; and SFY 1998 \$1,660,373.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that federal revenue collections for the Medicaid Program will decrease by approximately \$2,468,955 for SFY 1996; \$8,492,653 for SFY 1996-1997; and \$4,246,327 for SFY 1998.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

It is anticipated that the providers of the Pharmacy and Hospital Programs will experience the estimated decreased expenditures of \$3,398,424 for SFY 1996; \$11,813,400 for SFY 1997; and \$5,906,700 for SFY 1998. It is anticipated pharmacy providers will experience the major portion of these reductions for the provision of their services and that hospital and physician providers will experience the remaining reimbursement reductions.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)
There is no known effect on competition and employment.

Thomas D. Collins Director 9605#061 Richard W. England Assistant to the Legislative Fiscal Officer